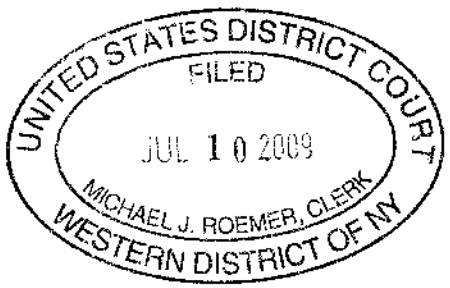
UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NEW YORK



09 CV 0630A(Sr)

Case Number

COMPLAINT

PATIENTS FOR MEDICAL JUSTICE LTD. (PFMJ)

Plaintiff,

-Against-

Defendants.

JAMES A. HALEY VA HOSPITAL
DECATUR VA HOSPITAL
AUDIE L. MURPHY VA HOSPITAL
PORTLAND VA HOSPITAL
LOUISVILLE VA HOSPITAL
DENVER VA HOSPITAL

INTRODUCTION

1. Plaintiff is a director of Patients for Medical Justice (PFMJ) assigned to ferret out fraudulent Veteran Administration device certifications and reimbursements of defective devices that are non FDA submitted and non FDA approved investigational biological combination devices. This is a request for information pursuant to the Freedom of Information Act (FOIA) 5 U.S.C. 552; FOIA 31 C.F.R. 1.5. (e) (2) (ii). For 6 months PFMJ has been seeking expedited processing of this duplicate request pursuant to U.S.C. 552 (a) (6) (E) (v) (ii) and [31 CFR 1.5 (c) (2) (ii). We are seeking copies of documents known to be in the control of the Veterans Administration.

2. Plaintiff, Patients For Medical Justice (PFMJ) LTD and Director James F. Allen bring this action against defendant Veteran Administration Hospitals and agency employees (staff) in vindicating PFMJ's right under the Freedom of Information Act (FOIA), 5 U.S.C. 552, to obtain on an expedited basis, known governmental records in reference to the VA's use of federal funds under the Veteran's Administration medical reimbursement program. Specifically records relating to Guidant Corporation's certification and reimbursement of public funds for implantation of six Ventak Prizm 2 DR 1861 combination biological Class III devices manufactured April 16, 2002 through November 13, 2002.

3. On information and belief Guidant Corporation used one (1) of three (3) investigational, non FDA approved, Non FDA submitted, off labeled, adulterated, misbranded adhesives namely **DERMABOND High and Low Viscosity, Nusil Med. 4870 or Rehau-Raumedic SI 1511** in "combination" with the Ventak Prizm 2DR 1861 Defibrillators. On information and belief April 16, 2002 through November 13, 2002 Guidant Corporation prepared approximately 12,926 investigational Class III medical devices and operated a non FDA approved, non FDA supervised, Non FDA submitted, experiment. These devices were placed or were caused to be placed into interstate commerce being wholesaled and retailed through Veteran Hospitals.

4. PFMJ requested records on the subgroup of devices because this subgroup was manufactured, wholesaled and billed to Veteran Hospitals including the six listed in this complaint. These devices were fraudulently certified by Guidant Corporation to be safe and effective/reasonable and necessary for their intended use as a "Combination" Biological Device. However, these "Combination" Biological Devices were and are experimental, investigational, non FDA Approved, non FDA Submitted, being two (2) Class III Life Sustaining Medical Devices combined into one brand new unapproved entity.

5. Under the Veterans Administration medical device reimbursement program the terms "experimental" and "investigational" have been used synonymously with each other. Therefore, these non FDA approved, non FDA submitted "Combination" Biological Devices were *not* "reasonable and necessary" or "safe and effective" within the meaning of the Veterans Administration's program. Thus reimbursement coverage is denied for the "Combination" Biological Devices. These devices were not and are not FDA Approved, FDA Submitted and entered the marketplace out of compliance with the status required by FDA Federal Regulations.

6. In 2001-2003 on information and belief Guidant Corporation developed a scheme to wholesale non FDA submitted, non FDA approved, adulterated, misbranded, experimental, investigational, off

labeled, Life Sustaining, Class III "Combination" Biological Devices. Guidant was experimenting with at least two (2) Biological devices in combination and on information and belief three (3) Biological device combinations. **(Dermabond High and Low Viscosity, Nusil Med. 4870 and Rehau-Raumedic SI 1511)** biological adhesives.

7. The devices were sold to the six (6) Veteran Administration hospitals listed on a consignment basis and paid for with reimbursed federal funds as the devices were used by the surgeons and implanted. The six hospitals operated with Guidant to provide the "combination" devices and lead systems. Guidant knew the "combination" biological devices were new and modified items and therefore not certified and not reimbursable.

8. Under the purchase ordering system, the VA Hospitals would use a device in stock and forward a replacement order signed by an authorized person at the particular VAMC hospital. Guidant would then bill for the device, leads etc.

9. Guidant would provide the mandatory quarterly report on sales by line item. The reports to the VA Hospitals included the name of the hospital, where the implantation was performed, the date of the implantation; the description of the model sold by Guidant (Ventak Prizm 2DR 1861), the serial number of the "Combination" Biological Device, the serial numbers of the leads and the pricing for each item.

10. *Guidant's invoices to the Veteran's Administration provided* the company's name, address, invoice number, phone, contract line items, order number, description of the devices purchased, unit measurement, unit price, extended price of items delivered, shipping number, date of shipment including the bill of lading number and weight of the shipment if shipped on Government bill of lading and terms of any discount for prompt payment offered. In 2003 all solicitation contract orders were sent out from the VA National Acquisition Center, Federal Supply Schedule Service; 1st Avenue; PO Box 76; Bldg. 37; Hines Il 60141 (Help Desk 1-708-786-7737). Guidant received its first contract in 2003 after selling devices to the VA since 2000.

11. The Government can not purchase and reimburse a Non FDA Approved, investigational "Combination" Biological Device without Biocompatibility training and Toxicology testing. [United States v. Regan 517 Fed 449 (7th Cir.2008)] [6]. The "Combination" Biological Devices were not contract devices, therefore, all governmental payments and the "Full Payment" exceeded the cost and was falsified

by Guidant. Guidant had billed the VA federal healthcare program directly and was reimbursed directly using a fraudulent certification.

12. On information and belief Guidant began to receive shipments of DERMABOND Low Viscosity Adhesive, DERMABOND High Viscosity Adhesive, Nusil Med. 4870 Adhesive and Rehau-Raumedic SI 1511 adhesive the first quarter of 2001 in preparation of the experiments. Starting on or about the first quarter of 2001 Guidant began the Non FDA approved, Non FDA Submitted, Non FDA Supervised experiments, with the creation of an off labeled "Combination" Biological Device. Food and Drug Administration states and records show these "Combination" Biological Devices were ***not*** FDA submitted or FDA approved. In fact, the "Combination" Biological Device, regardless of the adhesive chosen, was off labeled, misbranded, adulterated, and without FDA approval and was ***not*** "safe and effective" or "reasonable and necessary" for its intended use and therefore not covered for VA reimbursement.

13. On April 16, 2002 through November 13, 2002 one (1) or more of several experimental adhesives was placed in "Combination" with 12,926 Guidant Ventak Prizm 2DR 1861 defibrillators. On information and belief none of the biological adhesives that were used in the experiment had been submitted for FDA approval for use in the "Combination" Biological Device.

14. Although using these experimental adhesives was very cost effective there were major disadvantages discovered with the final adhesive that had been chosen and placed in combination with the investigational Non FDA approved defibrillator. The adhesive was being used off labeled as insulation for a High Voltage Wire and as an adhesive bonding material attempting to keep the "Header Connector Junction Device" adhered to the inside wall of the Titanium Can.

15. The 12,926 units being used in the investigational development of the "Combination" Biological Devices were non FDA Submitted, non FDA Approved, and Class III medical devices. The combination had produced a Brand New Life Sustaining device that was being used in a non FDA Submitted, non FDA supervised human clinical trial without the patient(s) consent or knowledge. The experiment failed causing serious injuries and deaths.

16. On or about February 2, 2004 Guidant employee Richard Roy in a statement regarding the disintegration of the polyimide used as the insulation on the high voltage wire and the adhesive glue bonding of the Header to the inside Titanium Can, stated that "guidant obtained fda approval" and repaired

a electrical shorting defect in 2002. Upon information and belief January 2001 through November 13 2002 one or more of experimental adhesives were placed in combination with the Ventak Prizm 2DR 1861 Defibrillators without FDA submission or FDA approval. In checking with the FDA and reviewing FDA Pre-Market Applications year 2001 through November 13, 2002, Dermabond Low and High Viscosity; Rehau-Raumedic SI 1511 or Nusil Med 4870 medical adhesives were *not* submitted to the FDA, as a "Combination" Biological Device, a filing necessary prior to any experimental or investigational use of any adhesive, creating a "Brand New" Combination Class III Medical Device. However, ***Guidant employees have stated that in 2001 through 2002 the company started a series of experiments with various adhesives, and changes*** in creating a "Combination" Biological Device.

17. Reviewing FDA records for Guidant Corporation and verifying the information found in 2001 through November 13, 2002 several Laws and Regulations were violated in the use of these Combination Biological Adhesive Devices by Guidant Corporation, including FDCA [21 CFR Part 807]. You must FDA register a new combination device [21 CFR 807.97], misbranding of a device and good manufacturing practices violations, [FDCA 501 (h)]; [21 U.S.C. 351 (h)]; [FDCA 520 (f)]; [21 U.S.C. 360j (f)]; [21 C.F.R. part 820]; the product combination did not have the quality that it purported to possess. [FDCA 501 (c)]; [FCDA 502 (f)]; [21 U.S.C. 352 (f)]; [21 C.F.R. 801.109]. The device was adulterated and misbranded; it lacked requisite FDA clearance and approval. [See FDCA 501 (f) 352 (o)]. Guidant had an FDA approved medical adhesive, the Tecothane TT-1075D-M Polyurethane (P910077/S010), for use as the Header Connector Top Material and the Titanium Can adhesive in mounting the Header inside the Ventak Prizm 2DR 1861 devices. The FDA approved brand ***(Tecothane TT1075-D-M Polyurethane Adhesive)*** was both "***Non Toxic" and "FDA Suitable for inside of a living body".*** The replacement and experimenting with the cheaper biological adhesives started 2001 through November 13, 2002 and, on information and belief, included the Dermabond High and Low Viscosity brand, the Nusil Med. 4870 and Rehau-Raumedic SI 1511. None of these devices were FDA approved for combination biological defibrillators.

18. These "Combination" Biological *Device changes were made prior to any approvals* and according to the FDA, the approvals and Engineering Correction Order 44770 that were reported to the plaintiff by Guidant employees Mr. Tich and Mr. Roy did not exist. FDA records showed that the changes were not made in any licensed application or investigational new device (IND). Not only was there no comparability testing there was no FDA filed testing at all. According to the FDA re-routing of a high voltage wire and the use of an experimental adhesive translates into significant changes in clinical safety and efficacy of a Combination Biological Device. This new device was the use of two investigational

devices "combined" into one (1) Experimental, Investigational, and non FDA submitted, and non FDA approved Class III medical device that failed.

19. Without testing and assessing the activity/potency of the two devices in combination and the measurements of the biological integrity of the products no consideration was given to in vivo and/or in vitro predictors of the biological effects in humans as with the FDA approved TT 1075 –D-M adhesive. With the changes made in the experimental adhesives 2001-2002 not even animal studies were completed with the combination investigational device.

20. The FDA did not know about the experiments and, therefore, was unable to determine the extent to which the different "Combination" Biological devices required testing. This was an unapproved combination biological device without application or submissions of the changes pursuant to [21 CFR 601.12 or [21 CFR 314.70(g)]. Guidant knew or should have known that [21 CFR 601.12] prescribed changes must be reported to the FDA, and "Brand New" Combination Biological Devices require full FDA PMA APPROVAL before being released into interstate commerce.

21. Due to a Guidant unreported secondary sterilization process rapid disintegration was occurring in the biological experimental adhesive that was chosen by Guidant from their non FDA reported, and non FDA approved testing 2001 through November 13, 2002. Rapid disintegration in several adhesive models is known to create formaldehyde which is toxic and carcinogenic. The chemicals from the adhesives begin to leach into the surrounding internal body tissue, body fluids and blood circulation system. In this case the adhesive that was chosen was used without FDA animal or human clinical studies in combination with the Ventak Prizm 2DR 1861 defibrillator and the experiment failed.

22. Since February 5, 1996 the FDA ***has allowed only one (1) adhesive*** to be used inside the defibrillators for the insulating, of the high voltage wire and bonding of the Header Connector Device to the inside of the titanium can wall. In the first quarter of 2001 through November 13, 2002, on information and belief, Guidant discontinued the use of the FDA approved adhesive and changed to the less costly group of experimental biological adhesives.

23. FDA Pre Market Application records show that the use of experimental adhesives was not FDA registered, namely, on information and belief, **Dermabond High and Low Viscosity, Nusil Med. 4870, and Rehau-Raumedic SI 1511** test adhesives were used and all failed. This experimenting was an off Labeled Use, and non FDA submitted or approved 2001 through 2002 experiment. The DERMABOND

High and Low Viscosity, Rehau-Raumedic 1511, and Nusil Med 4870 adhesives 2001 through November 13 2003 were not FDA Submitted or FDA Approved, for the "Combination" Biological Ventak Prizm 2DR 1861 Device for human clinical testing or any other use.

24. Starting December 2008 through May 9, 2009 PFMJ requested a fee waiver under [5 U.S.C. 552 (a) (4) (A) (i)] of the Freedom of Information Act, effective April 25, 1987]. The Plaintiff began requesting the *known to exist information* from the six VA hospitals listed in this filing. The information was reported to exist by three of the leading VA administrators. The information is known to exist as without the information being provided by Guidant to the VA Hospitals it would have been impossible for the 6 surgeries and reimbursement payments to have occurred 2002-2003. Although the Plaintiff had reduced his request to one (1) known device per hospital, in excess of 225 transactions were reimbursed to Guidant for the fraudulent certification of the "Combination" Biological, Non FDA Approved devices, 2002 through 2003.

25. Starting in December 2008 the Plaintiff requested the first set of FOI information from the Portland VA Hospital, Ms. Mary Knudson, and Mr. Brian S. Roth. The plaintiff provided the first name of the patient, the model of the device, the manufacturer of the device, the patient's device serial number 239693, and the implantation date of January 13, 2003 of the "Combination" Biological Device. Plaintiff explained that the information the Plaintiff had requested required the 20 day business request under the FOIA regulation to be completed, explaining that the device was a non FDA approved, adulterated, misbranded, toxic, carcinogenic, and investigational device.

26. Plaintiff, upon information and belief listed the 9 known chemicals including Formaldehyde, Hydrogen Cyanide Gas (Asphyxiate), Coal Tar (Bituminous Coal), Bisphenol A, D-n Octyl Phthalates, 1, 4 Benzoquinone, Methacrylate derivates, Hydroquinone, and D & C Violet #2 additive materials that are found in one of the experimental adhesives and reported that these chemicals were known to leach into the body, body tissue and blood of the unconcenting and unknowing Veterans. The plaintiff further provided the results of the defective device, including the nerve damage, needless storm shocking, further heart damage, additional surgeries, chemical poisonings, serious injuries and deaths that have occurred.

27. The Plaintiff provided copies of his personal device reporting to the FDA which was published and released by the FDA to the physicians February 7, 2006 along with copies of the United States Department of Justice cases that clearly showed the item copies requested in the FOIA were provided to

each hospital in a clear narrow request from the Plaintiff for identifiable and immediately releasable documents.

28. On January 5, 2009 Mr. Brian S. Roth Deputy FOIA/Privacy Officer attempted to force the Plaintiff to provide the Social Security Number, date of birth, etc., of the Veteran patient involved, in order to fulfill, the Plaintiff's Freedom of Information Act request. This was in every respect a total violation of the Act and deliberate attempt to destroy the meaning of the law. First, the Plaintiff in no way had requested any personal information of the Veteran or the physician who had performed the surgery and the information provided by the Plaintiff to Mr. Roth had come from VA files. Mr. Roth knew there was no reason to ask the impossiable from the Plaintiff to deliberately prevent the FOIA from being completed. More than enough information was provided for Mr. Roth to ferret out the request in full.

29. Secondly Mr. Brian Roth's further statement of "we do not have responsive records to your request" *"as it is written."* must be carefully analyzed as to the true meaning of this type of behavior as the Plaintiff would soon discover these attitudes permeate throughout these 6 hospitals with total disrespect for even the lives of the remaining approximately 5,000 patients. As of October 6, 2007 (7,925) of these devices have fail prematurely causing serious injuries and countless deaths not to mention approximately $303,000,000 to $431,000,000 Million dollars of VA and Medicare Fraudulent reimbursements of Federal Funds have been paid to Guidant.

30. Excuses for not complying and ferreting out the requests are wide spread outside the FOIA laws, and have ranged from send the names of the patients, social security numbers, and dates of birth to you should appeal to General Counsel, to these are none disclosure records, to Denver does not implant defibrillators, to just forward your request to Atlanta, to the VHA VA Central Office, Washington DC does not maintain such records, to VHA FOIA must administratively close your request at this time, and finally all of these time consuming practices were funneled into "you will have to speak with Timothy Graham" Acting FOIA, Washington DC. After a return letter from Mr. Graham explaining in part "The results of the consultation determined that the VHA VA Central Office located in Washington, DC does not maintain such records and does not have a copy of any such records." "We are therefore returning your request to the Atlanta (Decatur) FOIA Office for processing of any records which would be in their custody." "The VHA FOIA OFFICE however must 'administratively closed' your request". Plaintiff turned to his attorney to speak to Mr. Graham, after this plaintiff threatened this suit and Mr. Graham assured the plaintiff in legal statements above the plaintiff's understanding, he would see that the request was tied up for good. The Plaintiff's attorney has spoken to Mr. Graham twice but after 6 weeks there have been 0 results.

31 Further, THE WE ARE LOST VA HOSPITALS REPLYS: Should you choose to file an appeal, clearly indicate why you disagree with each determination, your request was denied, "no records found, all records or information compiled for law enforcement purposes which if disclosed, could reasonably be expected to constitute an unlawful invasion of personal privacy have been withheld, the implant was not done at this facility, the exemption noted in that letter were incorrectly cited, the Prosthetics department reviewed their records for the request "no records found", after an extensive search we were unable to locate any information, Guidant did not have a national contract with the VA in 2002, the VA Medical Center, Louisville does not have any information, I sincerely apologize for the delay.

32. With 42 correspondences in writing and countless phone calls and faxes involving 6 patients, 6 Medical Devices, 6 hospitals, information that for a fact is listed within the VA Hospital Medical System, as being implanted and government reimbursed, not one Veterans Administration employee including the following, could take the time and comply with federal law, ferreting out the location of 3 maybe 4 pieces of paper, for each hospital, 6 transactions Guidant Defibrillator sales, and VA reimbursements, that are without question in the VA system.

33. The following individuals in one way or another have denied the existence of known VA records, required by federal law in the reimbursement of the 6 defibrillators, 2002 through 2003. Dr. Edward Keung, Director, Brian S. Roth, Mary Knudson, Mr. Ronald Jones, Ms. Paula Marti, Mr. Dennis Horton, Ms. Rhonda Aldridge, Mr. James Stansky, Ms. Vicki MacDonald, Mr. Jeffery Milligan, Mr. Steven A Thomas, and Ms. Delena C. Bidwell.

34. The Plaintiff sought expedited processing pursuant to [5 U.S. C. 552 (a) (6) (E)] because of the self evident importance of the timely dissemination of information on these rapidly disintegrating medical devices and the need to warn the remaining 5,000 patients who are still implanted with the failing "combination" biological devices, allowing their physicians to guide them as to their alternatives. The Plaintiff, having been unable to obtain even a timely response to its application for expedited processing as required by [5 U.S.C. 552 (a) (6) (E) (ii)-(iii)] and 31 CFR 1.5 (c) (4)] PFMJ is now seeking declaratory and injunctive relief from this Court.

35. [See FOI requests and denials dated] December 17 2008 – Ms. Mary Belle Knudson; December 23 2008- Ms. Mary Belle Knudson; January 5 2009 – Brian S. Roth; January 24 2009 – Dr. Edward Keung; January 25 2009 – Dr. Edward Keung; January 25 2009 – Mr. Ronald Jones; January 25

2009 Mr. Bryanne Patail; January 26 2009 – Mr. Timothy H. Graham; January 30 2009 – Mr. Timothy H. Graham; February 5 2009 – Ms. Paula Marti; February 12, 2009 - Brian D. Roth; February 19 2009 – Ms. Rhonda Aldridge; February 19 2009 – Ms. Mary Belle Kundson; February 23 2009 – Ms. Mary Belle Kundson; February 23 2009 – Mr. Jack Humphries; February 23 2009 – Ms. Rhonda Aldridge; February 23 2009 – Mr. Dennis Horton; February 24 2009 – Mr. Humphries; February 24 2009 – Mr. Glen W. Grippen; February 24 2009 Mr. James Stansky; February 24 2009 – Ms. Vicki MacDonald; February 24 2009 - Ms. Rhonda Aldridge; February 24 2009 – Mr. Brian S. Roth; February 24 2009 – Ms. Mary Rhonda Aldridge; February 25 2009 – Ms. Paula Marti; March 1 2009 - Mr. Timothy Graham; March 2 2009 – Mr. Jeffery Milligan; March 3 2009 – Ms. Paula A. Marti; March 6 2009 – Ms. Rhonda R. Aldridge; April 16 2009 – Mr. Steven A. Thomas; and May 5 2009 – Ms. Delena C. Bidwell .

36. The need to provide the public, FDA and 5,000 remaining patients and their physicians with information contained in the VA requested records is especially urgent in light of the immediate crisis in the health industry, the lives of the remaining patients and the effect of the $ 431,000,000 million dollar fraud of public funds. Hundreds of millions of dollars paid for non FDA submitted, non FDA approved. Non VA certified investigational, experimental devices that have caused nothing but injuries and deaths. This type of criminal behavior, the sale of fraudulently certified VA approved devices, is one of the direct causes of the health care industry layoffs and teetering companies struggling to remain solvent. Unprecedented amounts of government capital, tax payer's dollars, have been drained from the VA heath care system with virtually no government oversight or desire to recuperate the theft of those funds.

37. Given the background and lack of transparency to date in the Veteran Administration's handling of the non FDA approved, non FDA submitted, the fraudulent certifications and VA hospital reimbursements, it is imperative that the public be informed promptly about the details of the risks involved with the "Combination" off labeled Biological failing devices. The VA and (6) hospitals has been well informed as this tragedy started in the third quarter of 2001. These "combination" biological devices have not been FDA filed or FDA approved for internal body use, FDA recalled, and were fraudulently certified for reimbursement, yet the VA continues to refuse to abide by the FOIA laws. There has been no public disclosure to the Veteran patients with regards to the conditions of their devices. These are non-consenting, unsuspecting, elderly human beings who have and will suffer extreme hardships now and in the future as this cover-up continues to be extended by the actions of VA non FOIA compliance.

38. This plaintiff is a triple wounded veteran who received needless storm shocking from this device, additional heart damage, and toxic nerve disintegration and now suffers from severe tremors and loss of arm and hand control as a direct and needless result of this criminal act.

39. This subgroup of the Veterans Administration hospitals, (6 each) has forgotten in our democracy the Freedom of Information Act (FOIA) causes accountability through transparency which is the most prominent expression of a profound national commitment to ensuring an open Government. At the heart of this commitment is the idea that accountability is in the interest of the Government and the citizenry alike. The VA should not keep known information confidential merely because public officials might be embarrassed by disclosure, because errors and failures might be revealed, or because of speculative or abstract fears. The VA has some of the top of the line, most modern technology in the United States, and disclosure of the FOIA in this case should have been timely. It is the VA, not the requester who is responsible in ferreting out the known information in full and providing those document copies in detail as requested.

40. As the status of the medical manufacturing industry has become increasingly dire there has been widespread recognition of the critical role the public confidence plays in the ability to trust the integrity of these companies. As Guidant was convicted of 10 felonies, (a Felon) was banned from further VA sales for the last (3) years and just recently reinstated; (January 2009) it would appear that this information would be of profound interest to the VA. It is self-evident that public confidence depends, in a large measure, upon the availability of information about the government's (VA's) interventions.

41. Likewise, an informed public is essential to the national debate that is currently being conducted in Congress. Accordingly, there is a compelling and immediate need for the documents PFMJ has sought. Plaintiff need not demonstrate that the VA excuses are totally improper. Rather, the VA has the burden of establishing that they are indeed applicable - something the VA can not and has not done. [See 5 U.S.C. 552 (a) (4) (B)] (Burden is on the VA to sustain its actions to date); [See also Currie v. I.R.S. 704 F.2d 523 (11th Cir. 1983)]. (Holding there is a presumption of disclosures unless, after a de novo review, the agency has carried its burden of proving the withheld materials are within one of the exemptions); [Moorefield v. US Secret Service 611 F. 2d 1021 (5th Cir. 1980,] cert denied [449 U.S. 909] (holding there is a presumption of disclosure and unless the government proves the information requested falls within a specific statutory exemption, materials must be made available on demand). Therefore PFMJ, James F. Allen Director has a statutory right to the information the Plaintiffs have requested in full and there is no

legal basis for the VA refusal to disclose the information in its entirety, without redaction, other than patient and physician names.

JUDISDICTION AND VENUE

42. This district Court has subject matter jurisdiction over this action pursuant to [928 U.S.C. 1331] and [95 U.S.C. 552 (a) (4) (B).] Venue is proper in this district under [5 U.S.C. 552 (a) (4) (B)], because PFMJ's principal place of business lies within this district and Guidant's salesman Mr. James Davis, upon information and belief, sold the off labeled combination devices to local VA hospitals.

43. The general philosophy of the FOIA is full (VA) disclosure unless information requested is exempted under clearly delineated statutory language, which it is not the case in this FOIA filing request.[Dep't of the Air Force v. Rose, 425 U.S. 352,260-61 (1976)]. The FOIA mandates a policy of broad disclosure of governmental VA documents when production is properly requested [5 U.S.C. 552 (a) (3)]. The VA agency may deny disclosure of its records only if the information falls within one of the nine (9) statutory exemptions to the disclosure requirements under [5 U.S.C. 552 (b)]; [Multnomah County Medical Soc'v v. Scott, 825 F.2d 1410, 1413, (9th Cir 1987)]. Inasmuch the VA under the FOIA has not met its legal duty to respond to PFMJ's request for expedited processing within the required time, PFMJ is relieved of any further obligation to exhaust further administrative remedies and is now entitled to appeal directly to the Court to enforce the dictates of the FOIA pursuant to [5 U.S.C. 552 (a) (6) (C)].

THE PARTIES

44. PFMJ is a New York State Not for Profit LTD Company with its principal place of business located at 488 Central Avenue, Suite A and Lancaster, New York 14086, endeavoring to expose medical industry patient injustice and industry fraud.

45. .Defendant VA is a Federal agency and has possession and control of the records and information that PFMJ is seeking, through its FOIA request.

BACKGROUND

46. The Veterans Administration is charged with the primary responsibility of implementing and overseeing their Federal Reimbursement Program for the purchase and implantation of the "Combination"

Biological Devices in question. During 2002 under the VA medical program the American people provided the VA with broad authority to stabilize the financial reimbursement system for the VA. In 2002 the VA required a $2.1 Billion dollar increase in "discretionary" spending. This increase was taking place at the same time and in the same year 2002 that approximately $431,000,000 million dollars was paid by Medicare and the Veterans Administration for non FDA approved Class III investigational medical devices in unlawful fraudulent certified reimbursements.

47. Since 2001 there has been mounting concern by both the public and national leaders about the lack of transparency and accountability in the VA's reimbursement program and use of such large quantities of public funds.

48. March 20, 2008, through an email one VA officer stated to the VA staff *"Given that we are having more and more compensation seeking veterans, Id like to suggest that you refrain from giving a diagnosis of PTSD straight out." "Additionally, we really don't or have time to do the extensive testing that should be done to determine PTSD".* This type of behavior is evidenced in several ways including the VA's refusal to provide the FOIA requested, evidence known to have been processed from the manufacturer Guidant through the hospitals and VA reimbursement program, but refused to the Plaintiff.

49. Federal FDA information (evidence) shows, along with no FDA PMA filings for the "Combination" Biological Devices, that the "combination" devices had never been FDA submitted or approval for the 2002 experimental and investigational changes. Accordingly, it is critical to be able to obtain information known to the VA to exist, so that along with the Medicare reimbursement examples, the Plaintiff can inform the public, FDA and remaining Veteran patients, their physicians and hospitals, how the money is being used and what measures were or were not taken to protect its interests.

50. This FOIA request was intentionally narrowed and tailored at the VA's request in meeting their demands, but the refusal to release the documents continues (6 sets of information) no more that 15 copied pages. Ours is a government of laws including the FOIA laws duly promulgated and laws duly observed. No one is above the law: not the executive, not any federal agency, not Congress, and not the Judiciary. [ACLU v. Dep't of Defense, 339 F. Supp. 2d 501 (S.D. N.Y. September 14 2004) (P&J, 08/30/04)].

51. On February 7, 2006 a warning prepared by the Plaintiff was published by the FDA on the non FDA approved devices and the investigational use and degradation of the off labeled experimental biological materials that failed.

PFMJ FOIA REQUEST

52. The Plaintiff narrowed and reduced the FOIA request from 225 to (6) copy sets of the Guidant billing submissions, certifications, and the (6) VA reimbursement copies to Guidant, along with the payment amounts. This request was then spread out among 6 VA hospitals, one (1) each. The device serial numbers, implant dates, hospital location, patient's first name, device models, and where the surgery and/or follow-up took place for Ventak Prizm 2DR 1861 Combination Biological Device were provided by Dr. Edmund Keung, at VA National ICD Surveillance Center, who received the information from Bryanne Patail, a head Bio engineer for the VA. The information and existence of the 6 devices was correct and was delivered to the physicians of the 6 patients June 2005, along with Ronald Jones VA National ICD Surveillance Center, intranet website (http://icd.sanfrancisco.med.va.gov).

53. For 170 days the Plaintiff has been told the information never existed.

54. The 6 VA hospitals provided the FOIA information to Guidant after the (6) patient's surgeries and implantations According to Dr. Edward Keung, who handles patient alerts, the information the plaintiff provided each hospital was correct, and therefore **the VA funding system files, on the reimbursements have to exist. These devices were implanted.**

55. These 6 hospitals sold, implanted or caused devices to be implanted in at least 225 Veterans. We are requesting the information on 6. If the 6 hospitals can not find the 6 devices the plaintiff requested the Plaintiff will except any replacement 6 with the information requested. The six must have been implanted July 18, 2002 through July 18, 2003. Ventak Prizm 2DR 1861 Devices, serial numbers 230796 through 243722.

56. These devices manufactured April 16, 2002 thought November 13, 2002, were non FDA submitted, non FDA approved, investigational, off labeled, adulterated, misbranded, "combination" biological experimental devices. These devices were fraudulently certified and VA reimbursed. Although the Plaintiff, as set forth herein, is in possession of examples of certain documentation relating to the fraudulent and criminal filings for the VA reimbursement activities, complete documentation to support the allegations herein is in the possession and control of the VA, and is far superior to that in possession thus far by the Plaintiff.

57. The Veteran's Administrations is mandated both by law and government policy to maintain each and every Ventak Prizm 2DR 1861 Biological "Combination" defibrillator that the VA reimbursed July 18, 2002 through April 16, 2003, serial numbers 230796 through 243722. The Plaintiff is requesting information on the 6 devices.

58. With respect to the filings and the (6) VA hospitals Guidant Corporation knowingly presented, or caused to be presented, to an officer or employee of the United States Government, one or more false or fraudulent claims for payment and approval of the Ventak Prizm 2DR 1861 Combination Biological Devices manufactured April 16, 2002 through November 13, 2002, marketed and sold July 18, 2002 through 2003, (Serial Numbers 230796 through 243722;

59.Knowingly made, used, or caused to be made or used by the (6) hospitals, false records, certifications, or statements to get one or more false and fraudulent VA Ventak Prizm 2DR 1861 "Combination" Biological Device claims paid or approved by the Government;

60. Conspired to defraud the Government by getting false and fraudulent VA claims allowed, approved and reimbursed; and

61. Other violations that are VA improper, including investigational device payments on non FDA approved "Combination" Biological Devices; in violation of [section 1862 (a) (1) (A)]; "Combination" Biological/Defibrillator; (6) six class III medical devices, without Pre-Market submission or Pre-Market Approval.

62. Upon information and belief the (6) hospitals accepted certification and billing paperwork for VA reimbursement from Guidant Corporation. The forms included standard language in which Guidant certified to the United States Government substantially as follows, on the Ventak Prizm 2DR 1861 "Combination" Biological Device subgroup; the Company certifies that the Ventak Prizm 2DR 1861 Combination Biological Device has been submitted to and approved by the FDA and Guidant has provided an accompanying electronically filed or manually submitted form and that to the Company's knowledge and belief, this report and statement is true, correct, complete and prepared from books and records of Guidant Corporation in accordance with applicable instructions, except as noted. Guidant further certifies that the Company is familiar with the laws and regulations regarding the provisions of VA health care services and that the devices identified were provided in full compliance with such laws and regulations.

63. As a direct and proximate result of Guidant's fraudulent and deliberate concealment of the non FDA submitted, non FDA approved, investigational, experimental, Ventak Prizm 2DR 1861 Combination Biological Devices manufactured April 16, 2002 through November 13, 2002, the (6) VA hospitals listed, were caused to accept direct reimbursement certified billings from Guidant stating full compliance with the applicable laws when, in fact, the certifications were rendered erroneous due to Guidant's false, fraudulent and criminal conduct.

64. Guidant knowingly and/or recklessly caused these (6) VA Hospitals to reimburse fraudulent claims to Guidant, who used false and fraudulent certification for the Ventak Prizm 2DR 1861 "Combination Biological Device reimbursements. The VA Government was reimbursing investigational, non FDA submitted, non FDA approved Class III medical devices, excluded items that were not "reasonable and necessary" for the diagnosis or treatment of the illness to improve the functioning of a malformed body member. Investigational use of Medical Biological adhesive experimental combination devices are not "reasonable and necessary" and therefore not approved for VA governmental reimbursement coverage.

65. Additionally, because of the patent urgency, after 6 months of delay, PFMJ has decided to invoke its rights under the FOIA to seek the requested records for the second time, on an expedited basis, 20 business days. The Veterans Administration has been improperly denying expedited processing. There were no "unusual circumstances" specifically described in the statute. There has been no "due diligence" used by the VA, in getting the information out to the requester, **(PFMJ).** PFMJ fully complied with the VA's request to narrow the search, fully negotiating and cooperating with the VA; however, PFMJ then was informed "that simply reducing the search from 225 to 6 requests did not mean the request fit the fastest tract."

66. The waiver of all costs is requested from the Court pursuant to [5 U.S.C. 522 (a)(4)(A)(III)], ("Documents shall be furnished without any charge... if disclosure of the information is in the public's interest because it is likely to contribute significantly to public understanding of the operations and/or activities of the government".) The Plaintiff feels the contribution to the 5,000 remaining patients implanted with the non FDA approved device is more than in the public interest.

67. The pattern of handling the requests in this matter has in itself formed a precedent, wrongfully using the preservation of the confidentially of commercial and governmental information within the VA control and possession, to purportally protect the effective and efficient operations of the agency. The

protection of a $431,000,000 million dollar fraudulent Medicare and VA pay out of public funds is not information in the opinion of th plaintiff, that a criminal court would be consider "sensitive commercial government information" and efficient operation of the Veterans Administration nor are the needless serious injuries and deaths that were caused in part, as a direct result of the payout of the $431,000,000 million dollars.

68. Guidant produced FDA filings for the public and physicians showing 22 deaths in the Ventak family of devices 2001-2004. Confidential records ferreted out from the FDA as a result of Senator John McCain's strong efforts in dealing with the FDA, produced the true number of deaths 2001-2004 amounting to 3,834 elderly citizens and the FDA's last reported information is now stating the reported numbers amount to less than 10% of the accrual deaths caused by these devices that went unreported and literally buried.

69. The VA staff's refusal to release the known information is nothing more than a refusal to take the necessary extended efforts and locate the files. Unless Guidant was paid on the side, under the table or is still waiting for their 2002 reimbursements the information requested is stored in the VA system somewhere. The refusal to release of information, whether intentional or not, extends the cover-up of the scheme and causes a strong effect of discouraging several requesters, by using steps to force the requester to wait while the staff checks with general consul to find a :"sound legal basis" standard to refuse the Plaintiff.

70. The real problem comes from the embarrassment of the VA agency providing a convicted felon (Guidant Corporation), not one but two awarded contracts to enter the VA system in a 3 year period of time and once again providing fraudulent certifications to be submitted, reimbursements for defective, toxic, carcinogenic, off labeled, investigational, experimental, non FDA submitted, non FDA approved, Class III "Combination" Biological Devices, used in non consenting, unknowing Veterans, experimenting without FDA approval, patient consent or qualified supervision.

71. These devices were in violation of the VA federal reimbursement system, and were without completed claims processing; incorrect coding; no FDA approval, a fraudulent certification and being used in an un-supervised non FDA approved human clinical trial for the development of the combination; no exempt number in the Master File; the VA is forbidden from paying for investigational non FDA approved devices.

72. The VA has a strong history of paying fraudulent Guidant Corporation billings and the refusal of FOIA requests that relate to Guidant Corporation. Less than 3 years after the VA suspended Guidant from the VA system they are back on board again. The Freedom of Information Act by law should be administered with a clear presumption: In the face of doubt, openness prevails. The VA should not keep information confidential merely because of the fact that Guidant, a convicted felon, managed to reenter the VA system for the second time in three years. The VA should have acted promptly and in a spirit of cooperation with PFMJ.

73. The VA surgeons, cardiovascular surgeons, cardiologists and electrophysiologist who implanted the (6) six Ventak Prizm 2DR 1861 "Combination" Biological devices, caused the reimbursement of the Guidant devices by forcing the VA hospitals to keep the devices and leads on consignment in storage to be reimbursed by the United States Government. The VA was paying for the devices on average $19,300.00 wholesale device/leads. On information and belief physicians, although on salary, would not bill for the surgery but must know who their patients were and control the information the Plaintiff requested.

74. *With each of the (6) implants Guidant was provided with a copy of a standardized report ("registration form"), which was addressed to Guidant in a postage prepaid envelope. This report identified the patient by name, address, Social Security Number, date of birth, the implanting health care facility, the implanting doctor, the following physician, the following hospital, the referring physician, the date of the procedure, the implanted or replacement medical device (by model and serial numbers), the implant leads used (by model and serial number). The positions of the implanted leads, the date of implant for both the acute and chronically placed leads, by model, serial number and date of implant. The explanted pulse generator (by model, serial number and date of explant) and any leads removed (by model, serial number, the date the leads were removed, the sales agent, who obtained the purchase order data (serial number, and billing prices paid,) by the hospital for the Ventak Prizm 2DR 1861 biological device sold on consignment. All data was relayed to Guidant.*

75. Guidant would then bill the VA hospitals collect the charge for the Ventak Prizm 2DR 1861 Biological Device and pay the salesman's commission. Tracking information during the relevant times herein was forwarded to the FDA. Guidant would then send another device to the VA hospital on consignment.

76. Guidant, by knowingly concealing that the Ventak Prizm 2DR 1861 "Combination" Biological Devices were non FDA submitted, non FDA approved, caused the VA hospitals (government) across the country to reimbursed Guidant for the investigational and experimental devices. Guidant, through the use of a fraudulent certification, submitted their billings directly to the VA who provided the payment (reimbursements). The false data was used to confirm the reimbursements nationwide for the Veteran patients. Guidant's concealment of the non FDA submitted, non FDA approval caused the hospitals to release the payments.

77. On information and belief one (1) of three (3) non FDA submitted, non FDA approved investigational biological adhesives, during experimental testing, namely DERMABOND low and high viscosity, Nusil Med. 4870 or Rehau-Raumedic SI 1511, were place inside the Ventak Prizm 2DR 1861 defibrillators forming two investigational, Class III medical devices, into a single investigational "Combination" Biological Device. The investigational and experimental changes were made the first quarter of 2001 through November 13, 2002 producing the investigational single entity to be placed inside the human body without a FDA supervised "Human Clinical Trial" or approval.

78. On information and belief Guidant knew or should have known that the concealment of the defibrillator/biological investigational/experimental "combination" brand new device was being submitted to the VA improperly for governmental reimbursements as an *unqualified* device.

79. Guidant salesmen attending these VA implant procedures would enter the computerized information, including the reason for the replacement of failed devices into Guidant's internal information system. If the (6) VA hospitals and VA system has misplaced (lost) the medical records, Guidant could be contacted by Dr. Edmund Keung at the VA National ICD Surveillance Center or Bryanne Patail the head Bio Engineer for the VA, and they can request the information from Guidant to complete the FOIA within 72 hours. Regulation states if Guidant chooses not to provide the information they are at risk of the loss of the VA contract which has already occurred once and the fact that the contract has just been renewed after a 3 year suspension in January 2009 it would, in the Plaintiff's opinion, stand to reason Guidant would fully coruperate.

80. Throughout the FOIA Plaintiff's request and consistent denials of the request for "Expedited Processing" request was explicit, as was the 6 months of all of the communications in detailing the urgencies of complying with the FOIA laws and regulations. The 5,000 remaining patients ***will*** suffer and

face further heart damage, additional surgeries, chemical leaching, needless storm shocking, and countless cases of death.

81. On information and belief one of the three biological adhesives that was involved in the 2001 through November 13 2002 combination experiments had been FDA banned from internal body use and none of the three (3) Medical biological adhesive devices have been FDA approved for use in combination with the Ventak Prizm 2DR 1861 defibrillator, inside the human body. Therefore the FDA unapproved "Combination" device, was used by the VA hospitals without certification.

82. The VA and certain staff defendants listed have refused to make the presumption of "openness" in this FOIA request, in violation of *Executive Order 13392 - Barrack Obama, signed, January 21 2009.* The process to provide information can not be accomplished without reasonable ferreting out of a FOIA requests. The remaining 5,000 out of 12,926 still are totally unaware of what is transpiring inside their bodies, nor does the public have any idea that approximately $431,000,000 dollars of their funds has been fraudulently certified and improperly reimbursed by the VA and other governmental bodies. The requested information is held for a fact by the VA, with three key points being missed by certain VA staff.

a. The VA agency personnel must alter their mind set in keeping with the President's vision and ***order.*** This is the first and most important step to achieve a new era of open and law abiding government agencies. The VA personnel must think differently about the FOIA, ***it is the law and not just a great idea if it comes easy.*** The VA is obligated and must focus on the principles set out by attorney General Eric Holder for the FOIA. Most importantly, the VA personnel should view all FOIA decisions in a total prism of openness, especially in light of this federal criminal act hoisted upon the families and Veterans who remain unknowing, unconcenting victims of this scheme. The purpose behind the FOIA has been ignored creating the loss of precious time by the VA. As previously stated, it is a sick feeling after surviving triple wounding to experience the damage from these devices, both to your remaining years and to your family.

B. As the Supreme Court has declared: FOIA is a means for citizens to know what their government is up to [NARA v. Favish, 541 U.S. 157 171 (2004)]; [quoting U.S. Dep't of Justice v. Reporters Comm. For [Freedom of the Press, 489 U.S. 749, 773 (1989).] The Court elaborated that "[t]his phrase should not be dismissed as a convenient formalism" [Id At 171 - 172]. Rather "[i]t defines a structural necessity in a real democracy." [Id. At 172]. The VA's transparency with accountability is a requirement of a democracy. Therefore the VA should keep the purpose of the FOIA-ensuring an open government - foremost in their minds.

c. The VA should have been mindful not to review records for the sole purpose of determining what can be easily discovered through half measured attempts. Instead, the request and records should have been reviewed in light of a critical need, especially with full knowledge that Ventak Prizm 2DR 1861 "Combination" Biological devices were ***(unquestionably), contaminated with (1) of (3) investigational, and experimental biological materials, in "combination". Two (2) Non FDA approved, non FDA submitted, Class III medical devices.*** The Plaintiff provided more than enough proof that the Combination devices were fraudulently certified, submitted by Guidant and reimbursed by the VA July 18, 2002 through 2003. The VA's belief that the agency does not have to segregate and release known information, whether the release involves boxes of materials, or as in this case, narrowed to 6 sets of materials, the VA is in direct conflict with the Attorney General and FOIA Law.

83. During the last 6 months the Plaintiff was passed around and around to the end result of we can't help you and the entire FOIA staff, knowing the records excised, had no idea where the records were filed. May 31, 2001 the VA amended [5 U.S.C. 552(e) (4)], "Systems of records, - Department of Veterans Affairs...Folder." **"The records will be retained at the Vet Center for 50 years ..."**

84. The following ***FOIA VA staff*** was unable to discover and had no idea where the surgery records for the VA Veterans were kept. Six (6) sets of Veteran records and known Guidant reimbursements of federal tax payer's funds were lost. Mr. Brian S. Roth; Dr. Edmund Keung; Mr. Timothy Graham; Mr. Ronald Jones; Ms. Paula Marti; Ms. Mary Kundson; Mr. Jack Humphries; Ms. Rhonda Aldridge; Mr. Dennis Horton; Mr. James Stansky; Mr. Glen W. Grippen; Ms. Vicki MacDonald; Mr. Jeffery Milligan; Mr. Steven A. Thomas; and Ms. Delena C. Bidwell; all FOIA staff, knowing Veteran Patient's lives were at risk. Not one staff member, knowing for a fact the information existed, could use the most sophisticated computerized, cost effective health care network in the United States to ferret out the FOIA request.

85. The Plaintiff provided each staff member with a copy printed **on Veterans Administration Stationary, published by the VA Central Office Dr. Edmund Keung, confirming the devices existed.** All VA physicians were warned to review all information sources, to ensure that no patients were missed, and for some reason these (6) and possibly 225 patient's records are missing, Guidant's reimbursement records and certifications are missing and the patient files are missing? The publication named the hospitals who either provided the surgery or handled the follow-up or both, the serial numbers of the devices were provided, the specific hospitals involved were listed, the dates the devices were implanted were listed, the Guidant model implanted was listed, and Mr. Ronald Jones, the VA National Registry for

ICD's (defibrillator implants) offered to help with any search, but December 2008 through May 5 2009, not (1) FOIA VA employee knew where the FOIA files requested could be located and Dr. Keung and Mr. Jones did not receive one phone call. FOIA states it is the VA Agency's responsibly to ferret out the information not the requester.

86. It has become more than apparent in knowing the status of the remain 5,000 patients and the previous VA refusal to comply with FOIA Law that the Plaintiff must use the Court system to get the proper Federal FOIA relief for the balance of the VA patients still implanted without their consent or knowledge, and being used as one would use a laboratory animal in a experiment, investigational, non FDA supervised, non FDA approved Human Clinical Trial.

PFMJ's REQUEST FOR EXPEDITED PROCESSING

87. With respect to this second request for expedited processing pursuant to [5 U.S.C. 552 (a)(6)(E)(v)(ii)], Plaintiff (PFMJ) Patients For Medical Justice LTD, has been involved in the exposure of the fraud, injuries, and deaths from a known, non FDA recalled, non FDA submitted, and non FDA approved "Combination" Biological Device, along with the dissemination of information to the public as referred to in [31 CFR 1.5 (e)(2)(ii)]. As to the urgency of its request (PFMJ) states:

88. PFMJ's request concerns matters of exigent and current interest to the American public. Specifically, the American public has a compelling need to be immediately and fully informed about the sale of off labeled, investigational, experimental, non FDA submitted, non FDA approved, and Life sustaining "Combination" biological devices, sold and implanted off labeled, adulterated, and misbranded. These combination biological devices were involved in a VA governmental oversight that attends to the qualifications and use of tax payer's public funds and VA officials in some cases whether intentional or not were furthering the fraudulent cover-up and scheme. Entities that have been charge with the responsibility to let none of this type of behavior occur.

89. Public confidence in the institutions of government and its private surrogates is important to the stability of and recovery of an already severely damaged health care system. Access to the requested information in full, without redaction other than patient/physician names, in PFMJ's opinion, is imperative to the public's confidence. As the plaintiff is one of the 12,926 victims of the criminal experiment and experienced the additional heart and nerve damage, additional surgery, hospitalizations, along with loss of

control if arms and hands, the plaintiff can personally attest that sunlight is the only disinfectant in bringing this lack of accountability and transparency to the attention of the American public.

90. In 2005, 4,300 of the devices had failed. By Oct 2007 the count had increased to approximately 7,500 plus. Any further delays on the part of the VA in the release of the FOIA requested information is further endangering the lives of the remaining victims without the benefit of consulting with their physicians as to what courses may be the best for them. In addition, any further delay would disrupt the public's ability to make its views known to public officials just as those officials are daily being asked to make critical and sweeping decisions based on limited information on the VA programs. Significantly, any delay will further undermine public confidence in the integrity and reliability of the VA, further eroding the American financial system.

91. With respect to the VA's non-granting or granting of the information, expedited processing and attempting to drag out a second filing that program expired on May 5, 2009. After 6 months the Plaintiff can no longer allow the critical need for this information to be disregarded. Pursuant [5 U.S.C. 552 (a) (6) (E) (ii) (I)].

92. As of the date of this filing the VA has not responded to PFMJ's FOIA application for expedited 20 business day processing other then informing the Plaintiff "no records found" or the "records do not exist". The information the Plaintiff is requesting ***does exist in the VA Files*** and therefore to be further mislead about a known fact is of no value to the remaining patients. With the VA's refusal to follow statutory law one can not stand still without becoming a partner in this cover-up by doing nothing.

FACTS

93. The VA failed to conduct an adequate search for known documents that exist regarding the Ventak Prizm 2DR 1861 "combination" biological devices, manufactured April 16, 2002 through November 13, 2002, (12,926) devices of which at least 10,080 were reimbursed with federal government funds. In response to PFMJ's FOIA VA request the VA has stated there were no records of the devices being implanted. Guidant, the manufacturer, operates under a nation VA contract since 2003 and prior to that sold devices to the VA starting December 8, 2000 without a contract. The Guidant program was set up in the VA hospitals with the physicians, and Guidant provided the Defibrillators Combination Biological Devices and their necessary leads under a consignment program to the VA hospitals. Guidant provided a fraudulent "Certification" in 2002, to the (6) hospitals for the off labeled, non FDA submitted, non FDA approved, adulterated, misbranded, experimental, investigational, Combination Biological Devices.

94. The billings and reimbursements for the 6 devices were billed directly from Guidant and reimbursed directly to Guidant from the VA. Those actions caused the (6) documentations to Guidant from the VA and from the VA to Guidant, and will complete the FOIA material information requested, whether paper or electronic copies, are provided in complying with the FOIA laws.

95. The data on these (6) VA transactions was collected and reported through an approved data collection mechanism for the VA patients to have been implanted with the device. VA records already show the devices were implanted. The data information requested by the FOIA and provided to the VA hospitals by Guidant Corporation on information and belief, reported a completed Human Clinical Trial, a PMA filing, a FDA submission, a FDA approval, and that the patients were provided informed consent.

96. All of these acts, human clinical trial reports and statements submitted to the VA hospitals were fraudulent statements and certifications. Guidant had experimented with several investigational Biological adhesive materials, including upon information and belief **Dermabond High and Low Viscosity adhesive, Nusil Med. 4870 adhesive and Rehau-Raumedic SI 1511 formulas,** placing them in "Combination" with the Ventak Prizm 2DR 1861 Defibrillator. This "Combination" was accomplished by using two (2) Class III investigational devices, forming one identity through combination, a brand new, non FDA submitted, non FDA approved, experimental investigational device.

97. These six (6) VA filings had to provide specific information in justification of a genuine issue of material fact and need for the Ventak Prizm 2DR 1861 Biological "Combination" experimental, investigational, adulterated, misbranded, combination defibrillator Guidant billings, and Guidant certifications. ***Those qualifications were and are non existent but the fraudulent commercial Guidant billing, certification, documents and VA reimbursements information and payment records are lost in the VA system?***

FIRST CAUSE OF ACTION

98. *(Violation of the Freedom of Information Act for improper withholding of known, agency records), [5 U.S.C. 552 (a) (3) (A)] and [5 U.S.C. 552 (a) (3) (A) (4) (B)].* The agency is required to make a good faith effort to conduct a search for the requested records, using methods that can reasonably produce the documents. [Oglesby, 920 F.2d at 68]. Because the agency is in possession of the records and

is responsible for conducting the search, the Court may rely on [a] *reasonably detailed affidavit*, setting forth the search terms, the type of search performed, and averring that all files likely to contain responsive materials (if such records exist) were search. [Valencia-Lucena, 180 F3d at 326]; [quoting Oglesby, 920 F.2d at 68]. The VA provided the Plaintiff with the information provided the hospitals, therefore the requested information was presented to the VA by Guidant and the VA paid the reimbursement based on those fraudulent materials and documents.

99. Not one of the requirements were completed or met for the VA United States Governmental funds to be reimbursed for the six (6) devices. The plaintiff is respectfully requesting copies of the 6 transactions that did occur for a fact. Summary judgement is inappropriate if a review of the records raises substantial doubt about the adequacy of the search.

100. Plaintiff on information and belief states the VA did not include copies of the Guidant billings, Guidant certification, or VA Guidant reimbursement copies. Guidant July 18, 2002 through January 23, 2003 sold (6) Ventak Prizm 2DR 1861 "Combination" Biological Devices, to the (6) VA hospitals, noted in this complaint. Those (6) hospitals implanted and followed the patients, or implanted those (6) devices, or followed those six (6) patients. All of these Federal documents are known to be stored with in the VA medical system.

101. PFMJ repeats and alleges all the allegations contained in paragraphs 1- 100 as if fully set forth.

102. The documents requested by PFMJ's FOIA constitute agency records subject to mandatory disclosure under the FOIA Law. Executive Order 13392 (December 2005) requires Federal Agencies, (the VA) to make their FOIA program "citizen-centered and result-oriented". The PFMJ information FOIA request is **not** exempt from mandatory disclosure. The VA in administering the Act must **not** overlook their obligation to focus on individual records that require disclosure, meeting the Act's primary objective of *"maximum responsible disclosure of government information"*. [FOIA Update Vol. XIV, No. 3 (1993)] OIP Guidance.

103. The VA FOIA program has improperly withheld the requested agency records from (PFMJ), in violation of [5 U.S.C. 552 (a) (3) (A)]...

SECOND CAUSE OF ACTION

104. For a Declaration that PFMJ is entitled to expedient processing of the FOIA Request within 20 business days.

105 PFMJ repeats and realleges al of the allegations contained in paragraphs 1-103 as if fully set forth.

106. PFMJ is primarily engaged in the exposure and dissemination of information to the patients that are harmed, to the FDA and the public, as referred to in [31 CFR 1.5 (e) (2) (ii)].

107. There exists compelling need(s), and an urgency to inform the 5,000 patients, the public, and the FDA about the information sought in PFMJ's FOIA request as is required by [5 U.S.C. (a) (6) (E),] requiring success in acquiring the FOIA known materials.

108. PFMJ has more than complied with all efforts with respect to the substantive and procedural rules governing request for records under FOIA, records known to exist as required by [5 U.S.C. 552 (a)(3).]

109. As a result of the VA failure to meet its statutory deadlines under [5 U.S.C. (a) (6) (E)], about the FOIA information and documents sought in the PFMJ request PFMJ has deemed to have totally exhausted its administrative remedies pursuant to [5 U.S.C. 552 (a) (6) (C) (i)].

110. As a result of the actual and justifiable controversy existing as to whether the VA has violated the FOIA by failing to grant PFMJ, for a 6 month period of time, expedited processing and the delivery of known to exist information used in the processing of each of Guidant's certifications, Guidant's billings, and the VA reimbursements. PFMJ is deemed to have totally exhausted its administrative remedies pursuant to its VA FOIA requests.

111. As a result of the foregoing PFMJ is entitled to a declaration that its FOIA requests be afforded processing, within 20 business days.

THIRD CAUSE OF ACTION

(For an Injunction Compelling Expedited Processing)

112. (PFMJ repeats and realleges all of the allegations contained in paragraph 1-111 as if fully set forth herein.

113. As a result of the foregoing, PFMJ is entitled to an injunction compelling the VA to afford its FOIA requests expedited processing within 20 business days.

FORTH CAUSE OF ACTION

(For a Declaration that PFMJ is Entitled to the Records Sought in Its Request)

114. PFMJ repeats and realleges all of the allegations contained in paragraphs 1- 113 as if fully set forth herein.

115. Upon information and belief, the records sought in PFMJ's FOIA request are in the custody and control of the VA. These documents were established July 18, 2002 through January 23, 2003 and have been confirmed to include Guidant Corporation billings and Guidant certifications and the hospitals reimbursements, all available and incorporated inside of the VA systems of ICD records.

116. Upon information and belief, the records sought in PFMJ's FOIA request are more than "reasonably described" as required by [5 U.S.C. 552 (a) (3)] and provided was the description, serial numbers, product manufacturer's name, the date of wholesale, the date of document creation, date of implant, device model, participating hospital, patient's name, have all been provided to the VA, and are in fact VA documents, on VA stationary. The evidence of the existence of the information being in the control of the VA is with strong particularly to permit and conduct an organized, non random search, narrowed to 6 sets of information including a copy of the Guidant billings, the Guidant certifications and the VA reimbursements of the dollars billed by Guidant, with serial number verification.

117. Upon information and belief, the records sought by PFMJ are in no way subject to any form of exemptions from public disclosure that are set forth in [5 U.S.C. 552 (b)].

118. An actual and justifiable controversy exists in that the VA has refused and failed to disclose known existing records held by the VA and sought in PFMJ's FOIA request.

119. As a result of the foregoing, PFMJ is entitled to a declaration that the VA is obligated to provide the Plaintiff with non redacted copies (other the patient and physician names) of the records sought in PFMJ's FOIA request in full.

120. On information and belief Plaintiff has found that the VA's assertion that the specific information requested is non-existent contains an averment or assertion suggesting that a search for responsive documents was undertaken for the first 6 month period in all locations and that the VA systems of records likely contain the documents responsive to the Plaintiffs request have already been developed. The Defendant fails to recognize that the information already provided by the Plaintiff proves beyond a doubt that the FOIA information requested by the Plaintiff in each of the (6) implants exists.

121. The Defendant in order to have had the information exposed by Dr. Edmund Keung, and provided by the plaintiff to the (6) hospitals, confirms that the Guidant Billings and Certifications were presented in order to have been able to reimbursed Guidant and we know the (6) devices were implanted.

122. On information and belief the Defendant has to date refused to perform an adequate search of all records, systems and record locations which contain this type of agency records and documents responsive to the FOIA request. Further, for the Defendant to state that the records requested are non existent is stating that the supplier/contractor Guidant Corporation was paid approximately $431,000,000 million tax payer dollars without billing the governmental systems and hospitals; that Guidant was able to bill for federal funds without device certification submitted to those hospitals; that Guidant's billings for reimbursements from those hospitals were not submitted to the VA and other Governmental hospitals; and that 10,000 plus Medicare and VA patients were implanted with non FDA approved, non FDA submitted, investigational, experimental, devices, without being accounted for by the manufacturer, or VA hospitals, who implanted these off labeled devices.

FIFTH CAUSE OF ACTION

123. (FOIA) [5 U.S.C. 552]; [Public Law 104-231] OIG, OAS, public reports are to be made available. [See 45 CFR Parts 5.] (FOIA Regulations)

124. The Ventak Prizm 2DR 1861"Combination" Biological Defibrillator Device system included a pulse generator containing electronics, batteries and two electrodes (leads) attached to the patient's heart

and the device. These devices are inserted or replaced with the so called permanent Defibrillators (1861 model), with Transvenous electrodes (s); atrial and ventricular. The VA should have never made the decision to allow a reimbursement of any transitional payments for these investigational devices. These "Combination" Biological/Defibrillators Devices were non FDA Submitted, non FDA approved, investigational, and experimental devices and were implanted by the VA hospitals without the consent or knowledge of the Veterans being used in the experiment. These patients were used in a non FDA supervised human Clinical Trial with devices implanted in patients with less than 30% of their heart performance.

125. These "Combination" Biological/Defibrillators devices were injected with one (1) of three (3) experimental, investigational biologic adhesives namely DERMABOND High and Low Viscosity, Nusil Med 4870 or Rehau-Raumedic SI 1511, placed in combination forming a brand new device (single investigational entity), non FDA submitted, non FDA approved, adulterated, misbranded, off labeled, and used in a non FDA approved unsupervised experiment,that failed.

126. These devices were not eligible for reimbursement by federal law, were fraudulently and incorrectly coded as certified devices. In accordance with the principles of the Freedom of Information Act [5 U.S.C. 552], and with the known facts and information that the VA controls, with respect to the FOIA, the information should have been released. [Public Law 104-231]. The VA records and documents requested in the Plaintiff's FOIA are to be made available to members of the public and PFMJ requested them without redaction other than personal names. The VA knowingly withheld the requested information and documents, including Guidant's billings, Guidant's certification records and VA Guidant reimbursements.

127. January 31, 2002, in accordance with the principles of the Freedom of Information Law [5 U.S.C. 552], as amended by Public Law 104-231], OIG OAS reports issued are to be made available to members of the public to the extent information contained therein is not subject to exemptions in the Act. [See 45 CFR Parts 5.]

PRAYER FOR RELIEF

127. **WHEREFORE,** PFMJ prays that this Court:

a. declare that PFMJ-James F. Allen Director is entitled to receive expedited processing within the 20 business days;

b. issue an injunction compelling the VA to provide PFMJ's request expedited processing within 20 business days;

c. declare that PFMJ is entitled to copies of records sought for the (6) devices, namely Guidant's billings, Guidant's certifications, and the VA Guidant's reimbursements, none redacted other than patient and physician names;

d. issue an injunction that the 6 sets of records (copied) paper or electronic, requested will contain the hospital names, Guidant's billings submissions to each hospital, the serial numbers of the 6 defibrillators and leads, the date of implants, and the individual device and lead costs, along with copies of each check issued to Guidant for each billing and;

e. award PFMJ reasonable attorney fees and other litigation costs under [5 U.S.C. 552 (a) (4) (E) (i) (ii)]; [5 U.S.C. 552 (a) (4) (E)] as amended by Openness Promotes Effectiveness in our National Government Act 2007, [Pub. L. No. 110-175 (4),]; [121 Stat 2524, 2525] and; (h) Grant such other and further relief as the Court deems just and proper.

Respectfully submitted, July 10 2009

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